

REMARKS

Applicants wish to thank the Examiner for the review of the present application. Claims 69-78 have been added, and claims 36, 37, 40, 45, 49 and 57 have been amended. No new matter has been added. Applicants note that claims 37-41 have been found to be allowable if rewritten in independent format. Amended independent claims 37 and 40 have been amended to incorporate independent claim 36. Applicants note that claim 40 was amended so as to be directed to a method of assessing the change of cartilage in a joint of a *mammal* over time (see the claims in the response dated January 6, 2004, and the office action dated March 31, 2004, in which claim 40 was found allowable if rewritten in independent format).

35 U.S.C. 102

Claims 36, 42, 43, 61, and 64 stand rejected under 35 U.S.C. §102(a) as anticipated by Eckstein et al., 1998 AJR 170; 593-597 (hereinafter Eckstein). Amended claim 36 requires determining the change in the thickness, width, area or volume of the cartilage between the initial and later times, wherein the change in thickness is determined, in part, by alignment using 3-D registration techniques.

Eckstein discloses a method of determining the cartilage thickness throughout the entire joint rather than at specific locations (see Eckstein at page 595, col. 3, lines 1-4). Maximal thickness measurements of the joint are shown in Eckstein, for example, at table 3. However, nowhere does Eckstein disclose determining the change of thickness using 3-D registration techniques, as required by amended claim 36.

Since Eckstein fails to teach or suggest determining the change of thickness using 3-D registration techniques, as required by amended claim 36, amended claim 36 is allowable over Eckstein. Dependent claims 42, 43, 61 and 64 are allowable for the same reason as claim 36, and are further allowable in view of the additional limitations set forth therein.

Claims 49, 51 and 52 stand rejected under 35 U.S.C. §102(b) as anticipated by U.S. patent 5,320,102 (Paul et al., hereinafter Paul). Claim 49 includes mapping the amounts of the biochemical component in three dimensions. Areas of abnormal joint cartilage are determined by identifying the areas having altered amounts of the biochemical component present, thereby making a three-dimensional map of joint cartilage.

The Examiner cites column 4, lines 31-34 and column 5, lines 28-32 of Paul as teaching “making a three-dimensional map of joint cartilage.” Applicants maintain that the portions of Paul cited by the Examiner are related to MRI *imaging techniques*; but not “making a three-dimensional map” as recited in claim 49. More particularly, Paul discloses gradient refocused echo (GRE) 3D volume acquisition. This imaging technique uses a 3-D Fourier transform for image reconstruction from the raw MRI signal; however the resultant images are 2-D slices of cartilage. Moreover, the analysis performed in Paul takes into account only individual 2-D slices, not accounting for neighboring slices so as to make a three-dimensional map (see Paul, for example, at col. 5, lines 17-40).

Addressing two-dimensional proteoglycan distribution profiles exclusively, Paul fails to teach or to suggest making a three-dimensional map, as cited in claim 49. Accordingly, the Paul reference is insufficient to anticipate claims 49, 51, and 52, and the rejection under 35 U.S.C. § 102(b) is improper.

Claims 36, 42, 43, 45-47, and 61-68 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. patent 6,560,476 (Pelletier et al., hereinafter Pelletier). As Applicants have already pointed out on the record, the earliest date to which the Pelletier patent is arguably entitled under 35 U.S.C. § 102(e) is November 1, 1999. The pending application claims priority from the December 16, 1998, filing date of a provisional application Serial No. 60/112,989. Accordingly, the Pelletier patent is not a proper reference at least with respect to pending claims 45-47 and 65-68. The rejection of these claims under 35 U.S.C. § 102(e) as being anticipated by Pelletier is therefore improper.

Support for independent amended claim 36 in the provisional application can be found as follows. Support for determining the thickness, width, area or volume of a region of cartilage at an initial time T_1 ; determining the thickness, width, area or volume of the region of cartilage at a later time T_2 ; and determining the change in the thickness, width, area or volume of the cartilage between the initial and later times, wherein the change in thickness is determined, in part, by alignment using 3-D registration techniques can be found, for example, at Appendix A, page 8, last full paragraph. Support for transferring an electronically generated image comprising the cartilage from a transferring device to a receiving device located distant from the transferring

device; and receiving the transferred image at the distant location can be found, for example, at page 6, 1st full paragraph. Support for converting the transferred image to a degeneration pattern can be found, for example, at page 7, section D.2.

Support for independent claim 45 in provisional application Serial No. 60/112,989 can be found as follows. Support for determining the thickness, width, area or volume of a region of cartilage comprising normal and diseased cartilage at an initial time T_1 using a magnetic resonance imaging (MRI) technique; determining thickness, width, area or volume of the region of cartilage at a later time T_2 using a magnetic resonance imaging (MRI) technique; and determining the change in the thickness, width, area or volume of the cartilage between the initial and later times can be found, for example, at Appendix A, page 8, last full paragraph. Support for performing a gait analysis, wherein the MRI technique and gait analysis includes placing external markers on the skin overlaying the bone on either side of the joint, the markers used to correlate morphological and biomechanical data, can be found, for example, at Appendix A, page 10, paragraphs 3 and 4.

At least for the reasons set forth above, Applicants submit that the rejection of claims 36, 42, 43, 45-47, and 61-68 under 35 U.S.C. § 102(e) is improper, and respectfully request that the rejection be withdrawn.

Claims 57-60 stand rejected under 35 U.S.C. § 102(a) as anticipated by Kshirsagar. Amended claim 57 is directed to a method of estimating the change of cartilage in a joint, and includes: defining a volume of interest around the region of the cartilage defect or diseased cartilage, whereby the volume of interest is equal to or larger than the region of cartilage defect or diseased cartilage, but does not encompass the entire articular cartilage; and computing any differences in cartilage within the volume of interest between timepoints T_1 and T_2 due to the cartilage defect or diseased cartilage.

Kshirsagar teaches “defining a cuboid plug of cartilage” at page 294, column 2, which the Examiner appears to equate with the “volume of interest” recited in claim 57. However, nowhere does Kshirsagar disclose that the volume of interest is equal to or larger than the region of cartilage defect or diseased cartilage, but does not encompass the entire articular cartilage, as required by claim 57. Instead, Kshirsagar discloses only that the cuboid plugs were performed at

four different locations on the femur (see Kshirsagar at page 294, column 2).

Additionally, the Examiner has identified Table 1 on page 295 of Kshirsagar as teaching measurement of differences in cartilage volume over time. However, the system described in the reference merely measures overall cartilage volume within a particular volume of interest, and does not compute differences in overall cartilage volume over time due to a cartilage defect or diseased cartilage.

Amended claim 57 recites, among other things, an element directed to “computing any differences in cartilage within the volume of interest between timepoints ... due to the cartilage defect or diseased cartilage.” The Kshirsagar reference does not teach this element. On the contrary, Kshirsagar’s cuboid blocks are “cut from the 3-D dataset” for interpolation and additional image processing (see Kshirsagar at page 295, column 1, lines 11-18). Kshirsagar’s repeated measurements reflected in Table 1 are not employed to measure differences over time due to the cartilage defect or diseased cartilage, but rather to evaluate interpolation methods operative to estimate total cartilage volume at a particular point in time (See page 295, column 1, lines 1-15). As with the Eckstein article discussed above, the focus of Kshirsagar is to determine the reproducibility of measurements using image analysis techniques (see Kshirsagar at page 290, column 2, lines 5-14), and not to identify differences in volume associated with cartilage degeneration.

35 U.S.C. 103

Claims 45-47 and 65-68 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Eckstein in view of Adams. Amended claim 45 includes performing a gait analysis, wherein the MRI technique and gait analysis includes placing external markers on the skin overlaying the bone on either side of the joint, the markers used to correlate morphological and biomechanical data.

At page 5 of the Office Action, the Examiner has cited Adams as disclosing “a marker for use with an MRI to be placed on the skin of an area of interest,” a feature admittedly lacking in Eckstein. However, nowhere does Adams disclose MRI technique *and gait analysis* that includes placing external markers on the skin overlaying the bone on either side of the joint, *the markers used to correlate morphological and biomechanical data*, as required by claim 45.

The combination of Eckstein and Adams thus fails to teach every element recited in independent claim 45, and the rejection of claims 45-47 and 65-88 under 35 U.S.C. § 103(a) is therefore improper.

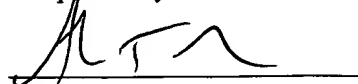
Claims 54-56 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Paul in view of Adams. The Adams reference does not supply the deficiencies of Paul. In particular, neither Paul nor Adams teach or suggest making a three-dimensional map as set forth above. Since the combination of Paul and Adams fails to teach Paul fails to teach or to suggest making a three-dimensional map, as recited in independent claim 49, the rejection of claims 54-56, which depend on claim 49, is therefore improper.

Claims 62 and 63 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Eckstein. Again, the Eckstein article fails to teach every element recited in the pending claims. At least for the reasons articulated above with specific reference to claim 36, the fair teachings of Eckstein are insufficient to render obvious claims 62 and 63. Applicants submit that the rejection under 35 U.S.C. § 103(a) is improper.

It is believed that the application is now in order for allowance and Applicants respectfully request that a notice of allowance be issued. It is believed that a three month extension of time is required for this matter. Applicant hereby petitions for same and requests that any extension or other fee required for timely consideration of this application be charged to Deposit Account No. 19-4972.

If the Examiner has any questions as to the allowability of the currently pending claims or if there are any defects which need to be corrected, the Examiner is invited to speak to the Applicant's counsel at the telephone number given below.

Respectfully submitted,



Alexander J. Smolenski, Jr.
Registration No. 47,953
Attorney for Applicant

Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110-1618
(617) 443-9292
03104/00105 566224.1